

Application No. 10/500,358
Attorney Docket No. 042276

Amendment under 37 C.F.R. §1.116
Amendment Filed: February 23, 2007

AMENDMENTS TO THE DRAWINGS

The attached sheet of drawings includes changes to Fig. 3.

REMARKS

Claims 1-18 are pending in the present application. Claims 13-18 are withdrawn from consideration. Claims 1-12 are rejected.

Claim Rejections - 35 U.S.C. §103(a)

Claims 1-9 are rejected under 35 U.S.C. §103(a) as being obvious over Clarkson et al. (US Patent Application 2001/0036964 A1) in view of McCue et al. (US Patent 5,403,587).

The Examiner notes that in the absence in the specification as to what exactly is the scope of a “cosmetically effective agent” and a “medicinally effective agent” the claims will be interpreted broadly so that the active agent disclosed by Clarkson et al. will read on both a “cosmetically effective agent” and a “medicinally effective agent”.

The Examiner then concludes that it would have been obvious to combine the antimicrobial compositions taught by Clarkson and McCue et al. with each other.

With respect to claims 7-9 directed to a medicine, the Examiner notes that in the absence in the specification as to what exactly is the scope of a “cosmetically effective agent” and a “medicinally effective agent” the claims will be interpreted broadly so that the active agent disclosed by in the deodorant of Clarkson et al. will read on both a “cosmetically effective agent” and a “medicinally effective agent”.

The Examiner notes that “deodorant” is described as a “cosmetic”. Furthermore, Examiner interprets the claim broadly and views a “deodorant,” which was defined by the

Applicant as “an agent that masks, suppresses, or neutralizes odors, especially a cosmetic applied to the skin to mask body odors,” as a “medicine for those suffering from body odor.”

Applicants respectfully disagree with the Examiner’s interpretation of the terms “cosmetically effective agent” and a “medicinally effective agent”, and with his rationale for concluding that the terms are synonymous.

Applicants have asserted that the terms “cosmetically effective agent” and “medicinally effective agent” are independent. Applicants have described the elements of cosmetics and medicines separately in the specification, and have claimed these agents separately in the claims. Therefore, there are clear indications that the terms are intended as separate terms. Moreover, Applicants have presented dictionary definitions of the terms that show that the terms encompass different meanings. Yet in spite of the above, the Examiner ignores the presented evidence of the distinctness of the claimed terms to reject the claims under the same disclosed deodorant of Clarkson et al.

The above terms have been used separately throughout the specification and throughout the prosecution of the present application. Applicants submit that a deodorant is clearly a cosmetic; it is not a medicine. Applicants point out that a deodorant is no more a “medicine” for those suffering from odor than “food” is a medicine for those suffering from hunger.

Applicants strongly reassert the distinctiveness of the term “medicine” versus the term “cosmetic” or “deodorant” with respect to claims 7-9

Claims 10-12 are rejected under 35 U.S.C. §103(a) as being obvious over Clarkson et al. and McCue et al. as applied to claims 1-9 in view of Jensen et al.

The Examiner admits that Clarkson and McCue et al. fail to disclose specifically a food product containing this composition. The Examiner notes that in the absence in the specification as to what exactly is the scope of a “nutritionally effective edible substance,” the claims will be interpreted broadly so that the active agent disclosed by Clarkson et al. will read on a “nutritionally effective edible substance.”

The Examiner notes that Jensen et al. teach anti-bacterial agents to be employed as an effective preservative for food products (col. 1, lines 34-56). The Examiner concludes that it would have been obvious to use the antimicrobial composition as taught by Clarkson and McCue et al. in food products. The Examiner reasons that a person of ordinary skill in the art would have been motivated to use the composition taught by Clarkson and McCue et al. in food products because “the anti-bacterial properties of 1,2-hexanediol and 1,2-octanediol can be used as a preservatives in food products to prevent spoilage and decomposition.”

Applicants maintain their disagreement with the conclusion of obviousness of claims 10-12, because the Examiner has still failed to present a proper suggestion to combine the cited references to reach the claimed invention.

Applicants note that neither Clarkson et al. nor McCue et al. provides any suggestion to use the compounds found therein in any food or edible substance.

Clarkson et al. is concerned with antiperspirant for use on human armpits and feet. McCue et al. is directed to sanitizing compositions used to sanitize countertops, tiles, porcelain products such as sinks and toilets, floors, windows, eating utensils, glassware, dishes, dental and surgical instruments. Applicants note that neither armpits nor toilets are commonly associated

with food, and while eating utensils, glassware and dishes are associated with food, the compositions used to clean them are not.

The Examiner cites Jensen as teaching that (some) anti-bacterial agents may be employed as effective preservative for food products. From the above, the Examiner concludes that this would have suggested to one skilled in the art that the anti-bacterial agents of Roetker et al. and Clarkson et al. could be used with food.

Applicants maintain that the above conclusion is not reasonable. Jensen teaches that *some* anti-bacterial agents may be used with food. However, Jensen teaches agents made *only* from *persea gratissima*, an extract from avocado trees. There is no express or implied suggestion that any other antibacterial agents, particularly materials selected from the group consisting of 1,2-heptanediol, 1,2-nonanediol, and 1,2-decanediol, may be used with food. Applicants note that there are millions of other anti-bacterial agents that exist, a majority of which are poisonous, deleterious to health or at least unpalatable, and there is seen no teaching or suggestion that the specific anti-bacterial hydrocarbons of Clarkson et al. or McCue et al. could be used with foods in the same way as the avocado derivative of Jensen.

The Examiner later concludes that it would have been obvious to use the antimicrobial composition as taught by Clarkson et al. in food products because “because the anti-bacterial properties of 1,2-hexanediol and 1,2-octanediol can be used as a preservatives in food products to prevent spoilage and decomposition.”

However, the only shown teaching that the anti-bacterial properties of 1,2-hexanediol and 1,2-octanediol can be used as a preservatives in food products to prevent spoilage and

decomposition is found *in Applicants' own disclosure*. Applicants note that the Examiner may not use Applicants own disclosure as a suggestion to combine other references. Such a conclusion amounts to impermissible hindsight, which may not be used to advance the rejection.

Therefore, Applicants disagree with the rejection of claims 10-12, and traverse it.

With respect to the above rejections of claims 1-9, Applicants characterize the three references used in the rejections, and then provide additional argument and data to refute the rejections.

US Patent Application No. 2001/0036964A1 to Clarkson et al.

The invention relates to an anti-microbial composition comprising polyhydric alcohol or derivative. Preferred polyhydric alcohols and derivatives thereof are of molecular weight 60 to 500. Particularly preferred materials are 1,2-pentanediol, 1,2- hexanediol, 1,2-octanediol. (Paragraph [0065])

When used on the human body, the compositions and methods of the invention are of greatest benefit when used on the most malodorous areas of the human body, for example the underarm areas or feet. (Paragraph [0001]).

Fragrance is also a desirable additional component in the compositions of the invention. Suitable materials include conventional perfumes. (Paragraph [0086])

US Patent No. 5,403,587 to McCue et al.

“Such essential oil include... citronella, eucalyptus, peppermint, camphor...”. (Column 3, line 61).

“It is the further object of this invention to provide aqueous compositions which can be used as sanitizers, disinfectants and disinfectant cleaners.” (Column 2, line 13).

US Patent No. 2,550,255 to Jensen et al.

The present invention relates to the preparation of a potent antibiotic substance, and it has to do more particularly with the concentration of an antimicrobial substance of plant origin. (column 1, line 1).

As a result of the search for antibacterial agents, naturally occurring antibiotic substances have been prepared from plants, animal tissues, molds, antinomycetes, yeast and bacteria, for example, penicillin from the mold penicillium notatum. (Column 1, line 34).

Yet another object of the invention is to provide an antibiotic substance which any be employed as an effective preservative for food products. (Column 1, line 53).

The Examiner has asserted that

“Clarkson et al. discloses that perfume may be added to the deodorant containing 1,2-hexanediol and 1,2-octanediol for the purpose of prevention of body odor. McCue et al. discloses citronella as a compound having antimicrobial properties. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, and then the claims 1-9 are rejected under 35 U.S.C. §103(a)”, and

“Jensen et al. discloses object of the invention is to provide an antibiotic substance which may be employed as an effective preservative for food products. Therefore It is prima facie obvious to use the antimicrobial composition as taught by Clarkson and McCue et al. on food, and then the claims 10-12 are rejected under 35 U.S.C. §103 (a).”

Applicants note that in the response to the First Office Action, Applicants asserted that the unexpected effects of combination of particularly identified 1,2-alkanediol and perfume according to the present invention. In response to Applicants’ argument, the Examiner stated the following in the outstanding Office Action.

(a) This is not persuasive because although synergism is disclosed in applicant’s specification, there is no raw data for how synergism was deemed for Table 1-3.

(b) There must be a side by side comparison with the closest prior art.

In order to reply to the above-examiner’s statement, Applicants submit the enclosed declaration. The declaration includes raw data and test result of the side by side comparison.

With respect to the assertion of lack of synergism

Applicants note the following data, which is the raw data for the Tables 1 to 3. It should be also noted that this raw data are read from the Figs. 2 to 9 in the present specification. From the following raw data, thus by reading such data from the Figs, Applicants confirm how synergism was deemed for Tables 1 to 3.

[Table1]

C.albicans		S.aureus		P.aeruginosa	
1,2-OD	thymol	1,2-OD	thymol	1,2-OD	thymol
1500	0	2250	0	3000	0
313	313	313	313	1250	1250
0	625	0	625	0	2500

[Table2]

C.albicans		S.aureus		P.aeruginosa	
1,2-OD	eugenol	1,2-OD	eugenol	1,2-OD	eugenol
1500	0	2250	0	3000	0
313	313	625	625	1250	2500
0	625	0	1250	0	5000

[Table3]

C.albicans		S.aureus	
1,2-OD	citronellal	1,2-OD	citronellal
1500	0	2250	0
1250	1250	1250	1250
0	10000	0	5000

[Table4]

C.albicans		S.aureus	
1,2-OD	terpinyl acetate	1,2-OD	terpinyl acetate
1500	0	2250	0
1250	1250	1250	1250
0	10000	0	5000

[Table 5]

C.albicans		S.aureus		E.coli	
1,2-OD	citronellol	1,2-OD	citronellol	1,2-OD	citronellol
1500	0	2250	0	1250	0
313	313	625	625	625	625
0	625	0	1250	0	5000

[Table 6]

C.albicans		S.aureus		E.coli	
1,2-OD	β -pinene	1,2-OD	β -pinene	1,2-OD	β -pinene
1500	0	2250	0	1250	0
1250	1250	1250	1250	1250	1250
0	20000	0	10000	0	20000

[Table 7]

C.albicans		S.aureus		P.aeruginosa		E.coli	
1,2-OD	Isobornyl acetate	1,2-OD	Isobornyl acetate	1,2-OD	Isobornyl acetate	1,2-OD	Isobornyl acetate
1500	0	2250	0	3000	0	1250	0
2500	2500	1250	1250	2500	2500	1250	1250
0	5000	0	5000	0	5000	0	5000

[Table 8]

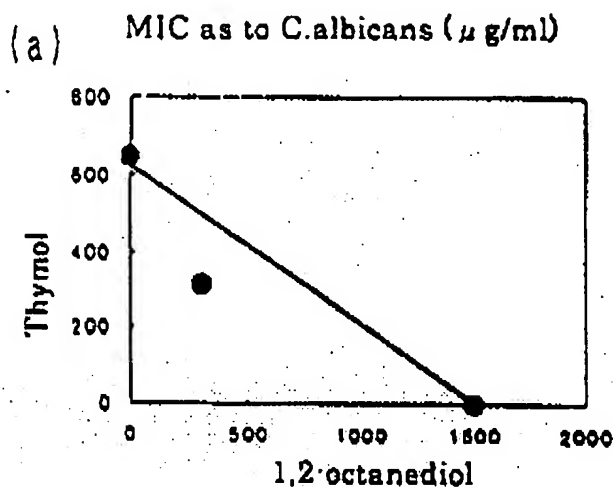
C.albicans		S.aureus		P.aeruginosa		E.coli	
1,2-OD	Guaiac acetate	1,2-OD	Guaiac acetate	1,2-OD	Guaiac acetate	1,2-OD	Guaiac acetate
1500	0	2250	0	3000	0	1250	0
2500	2500	1250	1250	2500	2500	1250	1250
0	5000	0	5000	0	5000	0	5000

Hereinafter, it will be explained how the above raw data can be read from the Fig. by referring to the Fig 2(a) related thymol in the original specification.

As described in the present publication No. 2005/0106191 [0054], 1,2-octanediol solution of 5, 4, 3, 2.5, 2.25, 2, 1.75, 1.5, 1.25 and 1 w/v % were prepared. Its corresponding data for MIC (MIC; Minimum Inhibitory Concentration) are 5000, 4000, 3000, ... 1250, 625, 313, ... µg.

While, as to thymol and the 50:50 by weight mixture of 1,2-octanediol and thymol, the dilution series were prepared by doubling diluting the solution to obtain solutions of 5, 2.5, 1.25, 0.625, 0.313 w/v %. Its corresponding data for MIC are 5000, 2500, 1250, 625, 313, ...µg.

Now, see the Fig. 2 (a) taken from the original specification.



According to the dual minimum inhibitory concentration diagram indicated in the Fig. 2 related to *C. albicans* (as to the procedure for making the diagram, see [0060] and [0061]), MIC for 1,2-octanediol is read from the point on the X-axis, and MIC for thymol is read from the point on the Y-axis. The read MICs are each 1500 μ g/mL and 625 μ g/mL.

The point of the 50:50 mixture by weight of 1,2-octanediol and thymol indicate its MIC, which is worth 625 μ g/mL (i.e., 313 μ g/mL of 1,2-octanediol and 313 μ g/mL of thymol)

For the other Figs 2 to 9, the above way can be employed for reading their MICs. As indicated in the present specification, compounds having low antibacterial activity were tested under the condition of concentration over 5w/v%.

As mentioned above, it is indicated by the raw data that particular 1,2- alkanediol and particular perfume synergistically act for its antibacterial effect. It should be also noted that an error has been found on Fig. 3 (C) (i.e., Fig. related to *P. aeruginosa*). The error is mere

inputting error during preparation of the diagram. This is because the different values of MICs for 1,2-octanediol and Eugenol (i.e., values of 1250 and 2500) are read respectively from the point of the 50:50 mixture by weight of 1,2-octanediol and Eugenol of the Fig. 3 (c). MIC of 1,2-alkanediol therein should have been the same as the one of the Eugenol therein. Therefore the Fig. 3 (c) has been deleted from the Fig. 3 in the present amendment.

With respect to the assertion of lack of side-by-side results

Applicants note page 5 of the declaration. Here is a side by side comparison with the closest prior art. For the prior art, 1,2-octanediol and the following samples were selected. Method for the test is indicated on the page 5 of the declaration, which follows the one described in the present specification.

[Table 1] Selected perfume, the essential oil or extract for the side by side comparison

perfume		Essential oil or extract	
*	Camphor	*	Citronella oil
	Farnesol)	*	Eucalyptus oil
	α -Bisabolol		Basil oil
	Limonene		striped bamboo extract

* Perfume, the essential oil or extract described in the McCue et al. (US Patent No. 5,403,587) which is cited in the Final Office Action.

Among perfume, Farnesol, α -Bisabolol, Limonene and Camphor were selected, and then tested.

Among the essential oil or extract known as having antibacterial activity, Citronella oil, Eucalyptus oil, Basil oil and striped bamboo extract were selected, and then tested.

For evaluating their antibacterial activity, the following bacteria are selected, which is all used in the embodiments in the present specification.

[Table 2] list of sample bacteria

1	Candida albicans
2	Staphylococcus aureus
3	Pseudomonas aeruginosa
4	Escherichia coli

The result of the side by side comparison test is shown in the page 6 of the declaration.

As indicated in the result, all tested samples show counteraction in its antibacterial effect against all tested strains when combined with 1,2-octanediol. Among them, Basil oil and striped bamboo extract showed additive action only against C. albicans, and none of the sample showed synergistic action (see the following Table 3 which is the same shown as Table 10 in the declaration).

[Table 3]

○: There is synergistic action in the antibacterial effect.

△: There is additive action in the antibacterial effect.

×: There is counteraction in the antibacterial effect.

Samples	Fig.	C.albicans	S.aureus	P.aeruginosa	E.coli
Farnesol	1	×	×	×	×
α-Bisabolol	2	×	×	×	×
Limonene	3	×	×	×	×
Camphor	4	×	×	×	×
Citronella oil	5	×	×	×	×
Eucalyptus oil	6	×	×	×	×
Basil oil	7	△	×	×	×
Striped bamboo extract	8	△	×	×	×

Finally, by comparing the Embodiments in the present specification of this case with the test results in the Declaration, it is concluded that only particular perfumes can enhance antibacterial activity that 1,2-alkanediol originally has, against a broad range of strains, thus only particular perfumes show synergistic action with the particular 1,2-alkanediol.

Thus, unless the particular perfumes and particular 1,2-alkanediol such as those indicated in the claims 1-12 according to the present invention, are selected, synergistic action in their antibacterial effect against a broad range of the strains can not be achieved.

In conclusion, because such synergistic effect obtained from combinations of such particular perfumes and 1,2-alkanediol is unexpected, and therefore can not be readily assumed by person in the art.

Therefore the present invention can not be rejected by the prima facie obviousness combining the cited references, the present invention described in the claims 1 to 12 is patentably distinct, and it should be allowed.

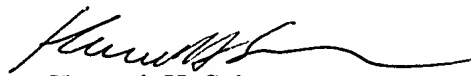
In view of the above remarks, Applicants submit that that the claims are in condition for allowance. Applicants request such action at an early date.

If the Examiner believes that this application is not now in condition for allowance, the Examiner is requested to contact Applicants' undersigned attorney to arrange for an interview to expedite the disposition of this case.

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP



Kenneth H. Salen
Attorney for Applicants
Registration No. 43,077
Telephone: (202) 822-1100
Facsimile: (202) 822-1111

KHS/rf
Enclosure(s): Declaration